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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,181	04/26/2001	Chris Sikorski	CER-298	9166

20311 7590 05/17/2005

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,181

Applicant(s)

SIKORSKI ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

1. The amendment filed February 22, 2005 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
 - (A) Claims 1-6, 8, 9 and 11-19 have been canceled;
 - (B) Claims 7 and 10 have been amended;
 - (C) Comments regarding Office Action have been provided drawn to:
 - (I) 112, 2nd paragraph rejection, which has been withdrawn;
 - (II) 103(a) rejection, which has been maintained for the reasons of record.
2. Claims 7 and 10 are pending in the case.
3. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Objections

4. Claim 7 is objected to because of the following informalities: In Claim 7, line 13, it appears that a comma should be inserted after the text "about 90% or more by weight of said product".. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. Claims 7 and 10 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al (US Patent No. 6,153,746) in view of Walsh (US Patent No. 5,980,971) or Fuentes et al (US Patent No. 5,756,484) or Giacobello (US Patent No. 4,127,944) for the reasons disclosed on pages 3-5 of the Office Action mailed October 20, 2004.
6. Applicant's arguments filed February 22, 2005 have been fully considered but they are not persuasive. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

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reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicants argue against the rejection on the ground that Applicants invention solved a problem (poor dissolution and dusting) that existed in the art and further discloses that the art, in the Fuertes et al patent, recognized the problem and solved it using a different solution than what is claimed. Applicants point out that the Fuertes et al patent solves the dusting and poor dissolution problem by spraying a slurry of hydroxypropyl- β -cyclodextrin onto a moving bed of pulverized hydroxypropyl- β -cyclodextrin. The Fuertes et al patent appears to solve the problem using drying techniques known in the art such as the spray dryer. However, the different solution to the dusting and poor dissolution problem disclosed in the Fuertes et al patent is not persuasive for patentability of the claimed invention since the Walsh patent, which is used in the rejection of the instant claims, suggests that it is obvious to substitute various drying techniques to produce dried, flake-shaped products, as instantly claimed. See column 6, lines 2-5 of the Walsh patent wherein various drying techniques are disclosed that include spray driers, drum dryers and others, which may be used to dry the product thereof. In response to Applicants's argument that the Fuertes et al patent solves the problems of the instantly claimed invention using a different solution, the fact that Applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicants amended the instant claims to recite the process as being applicable to a hydroxypropylated- β -cyclodextrin product as opposed to a modified cyclodextrin product. Although, the Shah et al patent is concerned with sulfoalkyl ether cyclodextrin, which is subjected to drum drying, the background information in the Shah et al patent does refer to preparation of hydroxypropyl- β -cyclodextrin. Shah et al having awareness of hydroxypropyl- β -cyclodextrin as having common utility with sulfoalkyl ether cyclodextrin, would substitute the sulfoalkyl ether cyclodextrin with hydroxypropyl- β -cyclodextrin to solve a problem that can be solved using a drum dryer. The Giacobello

patent is cited to show that the use of a drum dryer to improve the agglomeration of a dried product is well known in the art.

Applicants further argue that the Sikorski Declaration submitted on September 13, 2003, finds differences in the properties between the spray dried product and the drum dried product to be surprising and unexpected for a cyclodextrin product. However, this argument is not persuasive since no support in the instant claims has been noted that the hydroxypropylated- β -cyclodextrin product, per se, regardless of the drying technique used, is patentable over the hydroxypropylated- β -cyclodextrin of the prior art (including prior art not of record). Accordingly, the rejection of Claims 7 and 10 under 35 U.S.C. 103(a) as being unpatentable over the Shah et al patent in view of the Walsh patent or the Fuenes et al patent or the Giacobello patent is maintained for the reasons of record.

Summary

7. All the pending claims are rejected.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

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9. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

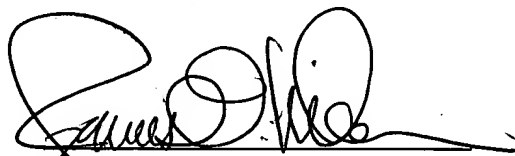
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



E.White



James O. Wilson
Supervisory Primary Examiner
Technology Center 1600